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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,316	12/30/2003	Jeffrey Robert Roose	1671-0286	8025

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Maginot, Moore & Beck LLP  
Chase Tower  
111 Monument Circle, Suite 3250  
Indianapolis, IN 46204-5109

EXAMINER
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LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
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3737

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,316	<b>Applicant(s)</b> ROOSE, JEFFREY ROBERT	
	<b>Examiner</b> Amanda L. Lauritzen	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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This action is in response to communications filed 29 July 2008. Amendments to claim 15 to specify a step of determining changes in the surface of the bone using the received positional data is interpreted as new matter. Rationale is provided in the new matter rejection under the first paragraph of 35 U.S.C. 112. New claim 21 additionally introduces subject matter not previously disclosed in applicant's specification.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Regarding objection to claim 18, applicant has pointed to a reference to Yuan et al. (cited as US 4,942,598) to suggest that the feature claimed of providing a reference pointer in the form of "an articulating arm with positional gyros mounted at pivotal joints of the articulating arm" is a conventional feature. However, Examiner notes that the patent number cited to Yuan et al as evidence is not actually to Yuan et al, but rather to Davis, so Examiner believes the patent number was cited in error and the objection is maintained and accordingly repeated herein since no verifiable evidence has been presented. Additionally no reference to Yuan et al is of record in the application file. Regardless, Examiner maintains that a reference pointer being embodied as "an articulating arm" and having "positional gyros mounted at pivotal joints" is not a conventional feature and must be shown in applicant's drawings if it is to be claimed because this phraseology is not conventional within the art and it is not clear what applicant intends to embody in the invention. Additionally since the reference pointer is recited in independent claim(s), it is regarded as an essential feature and the details claimed in claim 18 must necessarily be shown or the features cancelled from the claim(s).

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Examiner maintains that the disclosure of Lang et al. (US 2003/0216669) includes fabrication of a surgical guide in the form of an aperture guide and/or template [0049]. Additionally a “surgical guide image” is generated [0028]. It is further pointed out that a prosthetic device is in fact a surgical guide. Applicant’s specification is ultimately directed to fabrication of a surgical prosthetic device, and a guide is provided in the form of a surgical guide image, which is analogous to that disclosed in Lang et al. Furthermore, since Lang et al makes use of surgical guides and because they are well known in the prosthetic surgical arts, fabricating a surgical prosthesis by the same method is regarded as an obvious variant in exercising the method since the resultant product could be used (and is broadly understood as) a surgical guide.

Regarding Carson et al, Examiner maintains that the reference is generally applicable to the surgical guide but modifies the rejection as appropriate to address the newly introduced claim limitations.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 18 and the drawings are objected to because the claim recites specific structure that is not depicted in the drawings. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “articulating arm with positional gyros mounted at pivotal joints of the articulating arm” of the reference pointer must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

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sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 15 has been amended to include a step of “determining changes in the surface of the bone using the received positional data,” but this feature cannot be corresponded to applicant's disclosure. Examiner has identified paragraph [0049] in that positional data are

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disclosed to represent data regarding an articulating arm joint and that the data is further used to determine movement of the tip of *the reference pointer*, 208, in space. Using positional data to determine movement of a tip of a reference pointer in space cannot be interpreted to encompass determining changes in the surface of the bone as claimed and is this amendment is therefore interpreted as new matter.

New claim 21 specifies that the registration module be further configured to identify a portion of a bone remaining to be excised based upon the received positional data, but this feature is not described in applicant's specification. The disclosure apparently makes no mention of identifying regions of bone to be excised. In paragraph [0038], removal of "portions of flanges" is specified but these understood as part of the implant and not part of the bone.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Providing a reference pointer in the form of "an articulating arm with positional gyros mounted at pivotal joints of the articulating arm" is critical or essential to the practice of the invention, but it is not clear what this exactly refers to because the phraseology is not conventional in the art and the feature is not depicted in the drawings so it is therefore not enabled by the disclosure. It is not clear how one would make and/or use the invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-7, 8-14, 15 and 17-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to nonstatutory subject matter. In order for a process claim to be patentable

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under 35 U.S.C. 101, per *In re Bilski*, it must be tied to another statutory class (such as a particular apparatus), or transform underlying subject matter (such as an article or materials) to a different state or thing. The claim(s) must positively recite the thing or product to which the process is tied, for example, by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example, by identifying a material that is being changed to a different state. In the instant case, the method steps presented are not tied to a specific apparatus and they do not positively recite any subject matter or material that is being transformed to a different state or thing. Claims 8 and 15 recite analogous system limitations but appear to be generally directed to a process that is absent of specific apparatus and/or tangible subject matter or material that is being transformed to a different state or thing.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US 2003/0216669 in view of Dore et al. (2003/0236473).

Lang et al. disclose a system and method for designing a surgical guide for a joint replacement prosthesis and delineate generating a bone surface image from bone CT image data ([0092], in which the bone surface image is a topographical map). Additionally disclosed is a method for superimposing an image of a prosthetic implant on a bone surface image [0028], [0030]. The disclosure of Lang et al includes fabrication of a surgical guide in the form of an

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aperture guide and/or template [0049]. Additionally a “surgical guide image” is generated [0028]. While Lang et al. disclose rapid prototyping and stereolithographic techniques, which are generally understood to include using control data from an image or image creating program, Lang et al. does not specifically address this feature. However, in the same field of endeavor, Dore et al. teach using image data to control implant construction, which results in “machine tool control data” [0016, Dore et al]. It would have been obvious to one of ordinary skill in the pertinent art at the time of invention to use image data to direct automatic construction of a prosthetic device, as taught by Dore et al.

Regarding claims 3-5 and 10-12, an intra-operative (surgical guide) image includes at least one marker [0096, Lang et al]. Lang et al. teach laser and/or cutting treatment of many materials, including polymer (resins) [0015-0016], and such processes are well known in rapid prototyping schemes.

Regarding system claims 13-14, the system of Lang et al. as modified Dore et al. is inherently capable of generating image data from an acetabulum bone and an acetabular cup and/or a femur bone and femoral stem.

5. Claims 15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (US 2002/0147455, now USPN 6,923,817).

Carson et al. teach generally an imaging system for tracking patient anatomy and implant prostheses. The memory ([0094] and Fig. 1) serves as a repository. A mouse [0094] serves as a pointing device/reference pointer and it is well-known to skilled artisans to use wireless pointing devices. Position and orientation image data are tracked in three dimensions [0089]. Images (and image data) are both registered and superimposed [0103], [0115]. The system is inherently



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capable for use in imaging an acetabular cup of acetabulum bone. Additionally, the system of Carson et al is specific to determining changes in the surface of the bone by, for example, determining what are termed "bone spike holes" using coordinate data [126]. Regarding claim 21, the system of Carson et al includes applying rules or intelligence to make suggestions to a surgeon as to soft tissue releases that are to be made in order to improve kinematics of the knee [0127]. This is corresponded to ligament balancing after bone resections have been made [0003]. The system is also capable of tracking the patella and resulting placement of cutting guides and the petallar trial position [0130]. Additionally, regarding claim 21, systems and processes are available to the surgeon that generate data based on position tracking and to provide cues, such as "suggesting certain bone modification steps," which would include identification of portions of the bone to be excised, as claimed [0006].

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. L./  
Examiner, Art Unit 3737

Amanda L. Lauritzen  
Examiner  
Art Unit 3737

/BRIAN CASLER/  
Supervisory Patent Examiner, Art Unit 3737